Formulasi dan Karakterisasi Serbuk Kering Inhalasi Rifampisin Carrier-Free dengan Penambahan L-Leusin dan/atau Amonium Bikarbonat = Formulation dan Characterization of Rifampicin Dry Powder Inhaler Carrier-Free with L-Leucine and/or Ammonium Bicarbonate

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Abstrak

Formulasi serbuk inhalasi rifampisin carrier-free dapat menghantarkan rifampisin dalam jumlah yang adekuat untuk menjamin efektivitas terapi tuberkulosis. Diperlukan serbuk inhalasi rifampisin dengan sifat aerodinamis yang baik agar dapat terdeposisi di paru-paru. Penelitian bertujuan untuk menghasilkan sediaan serbuk inhalasi rifampisin yang memiliki sifat aerdonamis yang baik dengan adanya penambahan l-leusin dan/atau amonium bikarbonat, dengan pelepasan obat yang baik dalam medium makrofag paru. Serbuk inhalasi rifampisin (F1) diformulasikan dengan leusin 30% (F2), amonium bikarbonat 2% (F3) atau kombinasinya (F4) dan dibuat dengan metode semprot kering. Serbuk yang diperoleh kemudian dikarakterisasi rendemen, kandungan lembab, ukuran partikel geometris dan aerodinamis, serta kelarutan dan profil disolusinya dalam medium simulasi cairan paru pH 7,4 dan medium simulasi makrofag paru pH 4,5. Penambahan leusin 30% (F2) berhasil sedikit memperbaiki sifat aerodinamis serbuk inhalasi rifampisin (F1) dengan diameter aerodinamis rata-rata 8,21 Î¼m, FPF 30,73% dan EF 42,60%, serta meningkatkan pelepasan rifampisin dalam medium simulasi makrofag alveolar (pH 4,5) menjadi 13,14 Â± 0.08% dengan peningkatan 1,62x dibanding serbuk rifampisin (F1).

.....A carrier-free dry powder inhaler of rifampicin formulations could deliver adequate amounts of rifampicin to provide the effectiveness of tuberculosis therapy. Inhaled rifampicin powder with good aerodynamic properties was required to be deposited in the lungs. The aim of the study was to produce a rifampicin inhaled powder that had good aerodynamic properties with the addition of L-leucine and/or ammonium bicarbonate, with good drug release in the medium of lung macrophages. Inhaled rifampicin powder (F1) was formulated with 30% leucine (F2), 2% ammonium bicarbonate (F3), or a combination thereof (F4) and was prepared by spray dry method. The obtained powder was then characterized by yield, moisture content, geometric and aerodynamic particle size, as well as solubility and dissolution profile in lung fluid simulation medium (pH 7.4) and lung macrophage simulation medium (pH 4.5). The addition of 30% leucine (F2) succeeded in slightly improving the aerodynamic properties of the inhaled rifampicin powder (F1) with an average aerodynamic diameter of 8.21 Î¼m, FPF 30.73%, and EF 42.60%, as well as increasing the drug release of rifampicin in the alveolar macrophage simulation medium (pH 4.5) to 13.14 Â± 0.08% with an increase of 1.62x compared to rifampicin powder (F1).